K010362

MAR - 7 2001

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Mike Flis
Date Prepared: January 30, 2001

2) Device name

Proprietary name: Accu-Chek Comfort Curve Test Strip
Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

We claim substantial equivalence to the current legally marketed version of the same device.

4) Device Description

Instrument Operating Principle -- biamperometry
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Comfort Curve Test Strips are used with the Accu-Chek Advantage and Accu-Chek Complete Meters. The Accu-Chek Advantage and Accu-Chek Complete systems are designed to quantitatively measure the concentration of glucose in whole blood. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous, arterial and neonate (including cord) whole blood samples; lay use is limited to capillary whole blood testing.

On December 8, 2000, Roche Diagnostics provided premarket notification of our intention to commercialize a modified version of the Accu-Chek Advantage Meter. The modified meter shall be named Accu-Chek Inform. The premarket notification was given file #k003846 and is still under consideration. Once that 510(k) is cleared, we shall update this device's labeling to indicate the test strip may be used in conjunction with that meter.

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510(k) Summary, Continued

Comparison to Predicate Device

Similarities The Roche Diagnostics Accu-Chek Comfort Curve test strip is substantially equivalent to the current legally marketed version of the same device. The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Comfort Curve Test Strips are used with the Accu-Chek Advantage and Accu-Chek Complete Meters. The Accu-Chek Advantage and Accu-Chek Complete systems are designed to quantitatively measure the concentration of glucose in whole blood. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous, arterial and neonate (including cord) whole blood samples; lay use is limited to capillary whole blood testing.
Test principle	Glucose dehydrogenase chemical reaction. The test strip employs the electrochemical principle of biamperometry. The instrument applies a voltage between two identical electrodes, which causes a small current to be created. The strength of that current is related to the glucose concentration in the blood sample.
Monitor coding procedure	Code chip is provided with each carton of test strips.
Minimum sample volume	4 μL
Test strip storage conditions	Store the strips at room temperature, less than 90°F or 32°C. Do not freeze.
Test strip operating conditions	Use at temperatures between 57° and 104°F and less than 85% humidity.
Quality control procedure	Tests should be run with liquid quality control materials whenever a new vial of test strips is opened or an unusual blood test result is obtained.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.

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Comparison to Predicate Device, Continued

Similarities, Contd.

Hematocrit range	20-65% for glucose measurements less than 200 mg/dl and 20-55% for glucose measurements greater than 200 mg/dl
Reportable range	10-600 mg/dL
Acceptable sample types	Capillary, venous, arterial, and neonate whole blood samples.
Warnings and precautions	For *in vitro* diagnostic use only.
Reagent stability	18 months
Reagent composition	Copied from test strip carton label (qty/cm^2): Potassium ferricyanide.....43.7% Glucose dehydrogenase*.....1.2% Buffer.....24.7% Stabilizer.....19.4% Nonreactive ingredients.....11.0% * (from *A. calcoaceticus*, recombinant from *E. coli*) Minimum at time of manufacture.

Differences

Feature	Accu-Chek Comfort Curve Test Strip (modified)	Accu-Chek Comfort Curve Test Strip (predicate)
Test time	25 seconds	40 seconds
Sample anticoagulants	Recommended sample anticoagulants are heparin and EDTA. Serum separator tubes are acceptable if whole blood is used immediately. Iodacetate or fluoride/oxalate should not be used as a preservative.	Recommended sample anticoagulants are heparin, sodium fluoride/potassium oxalate, and EDTA. Serum separator tubes are acceptable if whole blood is used immediately. Iodacetate should not be used as a preservative.

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Comparison to Predicate Device, Continued

Data demonstrating substantial equivalence	Performance testing on the modified Accu-Chek Comfort Curve Test Strip demonstrated that the device meets the performance requirements for its intended use. A multicenter performance study was conducted to evaluate the accuracy and precision of the modified device. The clinical data demonstrates that the performance of the Accu-Chek Comfort Curve correlates well with the laboratory blood glucose reference test method. All predetermined acceptance criteria were satisfied. The data also demonstrates that the Accu-Chek Comfort Curve Test Strip is substantially equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 7 2001

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K010362
Trade Name: Accu-Chek Comfort Curve Test Strip
Regulatory Class: II
Product Code: LFR
Dated: February 2, 2001
Received: February 6, 2001

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K010362
Device Name: Accu-Chek Comfort Curve Test Strip

Indications for Use:

The Accu-Chek Comfort Curve Test Strips are used with the Accu-Chek Advantage and Accu-Chek Complete Meters. The Accu-Chek Advantage and Accu-Chek Complete systems are designed to quantitatively measure the concentration of glucose in whole blood. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous, arterial and neonate (including cord) whole blood samples; lay use is limited to capillary whole blood testing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010362

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)